

Application No. 10/790,640  
Amendment dated February 17, 2009  
After Final Office Action of November 17, 2008

Docket No.: 103080-P04-026

## REMARKS

### Claim Status

Upon entry of the amendments, claims 1, 3-8, 10-16, 21-25, 27-36, and 106 constitute the pending claims in the present application. Applicants have cancelled claims 40-67, which were previously withdrawn as being directed to a non-elected invention/non-elected species. Applicants have also cancelled claims 17-20, 26, 37-39, and 68-105 without prejudice. Applicants reserve the right to pursue the subject matter of the cancelled claims and to pursue claims of similar or differing scope in future applications. Applicants have currently amended claims 1, 6, 7, 13, 14, 21-25, and 27. Specifically, Applicants have added the term "non-human" to claims 1, 6, 25, and 27 to further point out the subject matter Applicants wish to claim; support for this amendment may be found in paragraph 39 of the published application. Claims 21 and 22 have been amended to recite "nuclear transfer of the mammalian primary cell, the nucleus from said primary cell or chromosomes from said mammalian primary cell". Support for this amendment may be found, for instance, in claim 1 as originally filed. Claim 23 has been amended to correct antecedent basis. The nature of the additional amendments, and support, are described below in the remarks directed to each rejection. No new matter has been added. Applicants have added claim 106 which is supported, for example, by claims 17 and 18 as originally filed. Applicants respectfully request reconsideration of the rejections in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

### Related Application

Applicants take this opportunity to inform the Examiner of a co-pending, commonly assigned application serial number 11/079,930. Applicants assume the Examiner is aware of this application because it was cited in the recent Office Action. Nevertheless, Applicants also wish to draw the Examiner's attention to the ongoing prosecution in this co-pending application. Applicants will be happy to provide copies of these applications or any papers associated with the prosecution of these applications upon request.

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Statutory Double Patenting Rejection

Applicants note with appreciation the Examiner's withdrawal of the 35 U.S.C. § 101 rejection.

Obviousness-type Double Patenting Rejection

Claims 1 was rejected on the basis of alleged obviousness-type double patenting over claims 1 and 4-6 of US Patent 6,808,704. Applicants respectfully traverse the rejection. Claim 1 of the instant application is not rendered obvious by claims 1 and 4-6 of US Patent 6,808,704 because, at least, claim 1 of the instant application recites "said mammalian primary cell is a senescent cell or a cell that is near senescence". Claims 1 and 4-6 of US Patent 6,808,704 contain no such limitation. In addition, claims 1 and 4-6 of US Patent 6,808,704 contain a step of "examining the injection site for teratoma formation and signs of rejection of the injected cells, or of teratomas derived therefrom, to test the immune compatibility of cloned cells or tissues." Claim 1 of the instant application does not recite "to test the immune compatibility." Accordingly, claim 1 of the instant application is not rendered obvious by claims 1 and 4-6 of US Patent 6,808,704.

In addition, claims 1, 3-8, 10-24, and 29-36 are provisionally rejected over claims 87-92 and 94-117 of copending Application No. 11/079,930. Applicants request that the Examiner hold this provisional rejection made under the judicially created doctrine of obviousness-type double patenting in abeyance until otherwise allowable subject matter is identified in the instant application. Once allowable subject matter has been identified, Applicants will evaluate the filing of a terminal disclaimer or providing arguments in view of the claims pending at that time.

Claim rejections under 35 U.S.C. §112, first paragraph, enablement

Applicants note with appreciation the Examiner's withdrawal of the enablement rejection.

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Claim rejections under 35 U.S.C. §112, second paragraph

Claims 1, 3-8, 10-28, 30-33, 69-71, 82-84, and 94-96 are rejected under 35 USC § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse the rejection to the extent it is maintained in view of the current amendments.

First, the Office Action rejects claims 1, 21, and 22 for use of the phrase “rejuvenating a primary cell.” The Examiner states, “the method as claimed does not result in modifying the cell per se,” but “rather results in a different and unique cell,” (page 4). Applicants have amended claim 1 to refer to two cells, “a mammalian primary cell” and “a cell of the same type as the mammalian primary cell” and have amended the preamble to read “A method of isolating a cell of the same type as a mammalian primary cell...” Support for this amendment may be found, for example, in part (f) of claim 1 as filed. Similarly, claims 21 and 22 have been amended to remove the term “rejuvenating”. In addition, claims 69 and 92, which recited the word “rejuvenated”, have been canceled. Accordingly, Applicants believe that claims 1, 21, and 22, and the claims depending therefrom (3-7, 23, and 24) are definite.

Next, the Examiner states, “Claims 7, 14, 82, and 95 remain vague and unclear because the nature of the alteration of the genome is not adequately described,” (page 5). Applicants respectfully traverse. Nevertheless, Applicants have amended claims 7 and 14, to remove the term “alteration to its genome” and to recite “has been transfected with at least one heterologous gene or has had at least one native gene disrupted.” Support for the amendment may be found, for example, in originally-filed claim 17 which reads “...wherein said genetic alteration comprises the transfection of at least one heterologous gene,” and originally-filed claim 18 which reads “...wherein said genetic alteration comprises the disruption of at least one native gene.” Claims 82 and 95 have been canceled. Accordingly, Applicants believe that claims 7 and 14 are definite.

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The Examiner also states, "Claim 13 remains unclear in the recitation of 'for transplantation into a patient in need of a transplant' because it is unclear if this is an intended use for the tissue or a limitation wherein the tissue generated must be capable of being transplanted," (page 6). Applicants have amended claim 13 to recite: "...a tissue suitable for transplantation..." Accordingly, Applicants believe that claim 13 is definite.

Next, the Examiner states that "Claim 25 remains confusing and unclear because an animal with the same genotype cannot be genetically different so cannot be altered... It is not clear what standard the term 'altered' is in comparison to," (page 6). Applicants have rewritten claim 25 to incorporate verbatim much of the text of claim 21 rather than referring to it. In addition, Applicants have removed the phrase "having the same genotype as the cell of Claim 24" from the preamble. Accordingly, Applicants believe that claim 25 (and claim 28, which depends therefrom) is definite. Claim 26, which depended from claim 25, has been cancelled. In addition, Applicants amended claim 24 (which refers to claim 21) to remove the term "genetically altered."

Finally, the Examiner states that "Claim 84 remains unclear because the metes and bound of the terminology 'substantially the same' is unclear." Applicants respectfully disagree, but nevertheless have cancelled claim 84.

Applicants believe that claims 8-12, 27, and 30-33 are definite. The recent Office Action listed these claims as rejected based on § 112 paragraph 2, but no specific rejections were made in the Office Action. In fact, the Office Action stated that the previous rejections of claims 8, 27, 32, and 33 were withdrawn. Thus, Applicants believe that claims 8-12, 27, and 30-33 are definite.

In light of the claim amendments and remarks above, reconsideration and withdrawal of the indefiniteness rejection is respectfully requested.

*Claim rejections under 35 U.S.C. §102(e)*

Applicants note with appreciation the withdrawal of the rejection of claims 1, 3-8, 10-20, 22-24, and 29-36.

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Claims 21, 25-28, 37-39, 69-78, 80-92 and 94-105 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Strelchenko *et al.* (US Patent 6,011,197) or Damiani *et al.* (US Patent 6,258,998). Applicants respectfully traverse the rejection.

First, the Examiner states that “claims 21, 69-78, 80-92, and 94-105 are product by process claims” (page 7) and states that “Such cloning products do not differ from any other standard cloning protocols that may differ in method steps from the claimed processes,” (page 7). Applicants note that claim 21 is in fact a method claim, reciting “A method of performing compound genetic manipulations in a mammalian primary cell, comprising...” Furthermore, claim 21 contains a limitation of “wherein said mammalian primary cell is passaged to a senescent or near-senescent state prior to nuclear transfer.” Applicants submit that the use of senescent or near-senescent cells for nuclear transfer is neither expressly nor inherently disclosed in any of the publications cited by the Examiner. Accordingly, Applicants believe claim 21 is novel.

Regarding claims 69-78, 80-92, and 94-105, Applicants believe these compositions of matter (e.g. cells) have material differences from cells described in the cited publications. Nevertheless, solely to expedite prosecution, Applicants have canceled claims 69-78, 80-92, and 94-105 and intend to pursue this subject matter in a continuing application.

Next, the Examiner states that “Claims 25-26 are drawn to recloning methods to result in a cloned animal wherein the donor cell has been genetically modified,” (page 7). Claims 25, as currently amended, recites the phrase “wherein said mammalian primary cell is induced into a senescent-like or near-senescent-like state prior to nuclear transfer”. Strelchenko *et al.* and Damiani *et al.* do not teach the use of senescent or near-senescent cells for nuclear transfer donors. Accordingly, Applicants believe that claim 25 and its dependent claim 26 are novel.

The Examiner also states, “Claim 37 merely requires transfer of a nucleus into a recipient oocyte,” (page 7). Applicants respectfully disagree. Nevertheless, Applicants have canceled claim 37 and its dependent claims (38 and 39).

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Accordingly, Applicants submit that claims 21, 25, and 26 are not anticipated by Strelchenko *et al.* and Damiani *et al.* Reconsideration and withdrawal of this rejection is respectfully requested.

Claims 21, 25-28, 37-39, 69-78, 80-92 and 94-105 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Robl *et al.* (WO 98/07841) as evidenced by Evans *et al.* (Nature Genetics 23:90-93, 1999). Specifically, the Examiner states, "the rejection is maintained over the product by process claims as the product fails to differ from that made by processes known in the art" Applicants respectfully traverse the rejection.

First, Applicants note that claims 21, 25, 27, and 28 are method claims, not product by process claims. Claims 21 and 25 contains a limitation of "wherein said mammalian primary cell is passaged to a senescent or near-senescent state prior to nuclear transfer," and claim 27 also refers to "a cell that is senescent or near senescence." Applicants submit that the use of senescent or near-senescent cells for nuclear transfer is neither expressly nor inherently disclosed in any of the publications cited by the Examiner. Accordingly, Applicants submit that claims 21, 25, and 27 (and claim 28, which depends from claim 27) are novel.

Regarding claims 26, 37-39, 69-78, 80-92, and 94-105, Applicants believe these compositions of matter (e.g. cells) have material differences from cells described in the cited publications. Nevertheless, solely to expedite prosecution, Applicants have canceled claims 26, 37-39, 69-78, 80-92, and 94-105.

Accordingly, Applicants submit that claims 21, 25, 27, and 28 are not anticipated by Robl *et al.* and Evans *et al.* Reconsideration and withdrawal of this rejection is respectfully requested.

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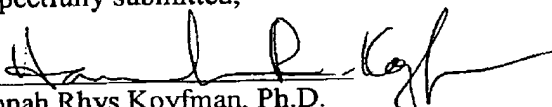
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### CONCLUSION

In view of the above remarks and amendments, Applicants believe the pending application is in condition for allowance. Applicants believe no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 18-1945, under Order No. 103080-P04-026 from which the undersigned is authorized to draw.

Dated: February 17, 2009

Respectfully submitted,

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